

**AMENDMENT IN THE NATURE OF A SUBSTITUTE**  
**TO H.R. 4365**  
**OFFERED BY M .** \_\_\_\_\_

Strike all after the enacting clause and insert the following:

1    **SECTION 1. SHORT TITLE.**

2        This Act may be cited as the “Protecting Patient Ac-  
3        cess to Emergency Medications Act of 2016”.

## 4 SEC. 2. EMERGENCY MEDICAL SERVICES.

5 Section 303 of the Controlled Substances Act (21  
6 U.S.C. 821 et seq.) is amended—

(1) by redesignating subsection (j) as sub-  
section (k); and

9 (2) by inserting after subsection (i) the fol-  
10 lowing:

11       “(j) EMERGENCY MEDICAL SERVICES THAT ADMIN-  
12       ISTER CONTROLLED SUBSTANCES.—

“(1) REGISTRATION.—For the purpose of enabling emergency medical services professionals to administer controlled substances in schedule II, III, IV, or V to ultimate users receiving emergency medical services in accordance with the requirements of this subsection, the Attorney General—

1           “(A) shall register an emergency medical  
2           services agency if the agency submits an appli-  
3           cation demonstrating it is authorized to conduct  
4           such activity under the laws of each State in  
5           which the agency practices; and

6           “(B) may deny an application for such reg-  
7           istration if the Attorney General determines  
8           that the issuance of such registration would be  
9           inconsistent with the requirements of this sub-  
10          section or the public interest based on the fac-  
11          tors listed in subsection (f).

12          “(2) OPTION FOR SINGLE REGISTRATION.—In  
13          registering an emergency medical services agency  
14          pursuant to paragraph (1), the Attorney General  
15          shall allow such agency the option of a single reg-  
16          istration in each State where the agency administers  
17          controlled substances in lieu of requiring a separate  
18          registration for each location of the emergency med-  
19          ical services agency.

20          “(3) HOSPITAL-BASED AGENCY.—If an emer-  
21          gency medical services agency is owned or operated  
22          by a hospital, and the agency is covered by the reg-  
23          istration of the hospital under subsection (f), the  
24          agency is deemed to have registered under this sub-  
25          section for purposes of this subsection.

1           “(4) ADMINISTRATION OUTSIDE PHYSICAL  
2 PRESENCE OF AUTHORIZING MEDICAL DIRECTOR.—  
3 Emergency medical services professionals of a reg-  
4 istrant emergency medical services agency may ad-  
5 minister controlled substances in schedule II, III,  
6 IV, or V outside the physical presence of the author-  
7 izing medical director in the course of providing  
8 emergency medical services pursuant to—

9           “(A) a standing order issued or adopted by  
10 one or more medical directors of such agency to  
11 the extent such administering is authorized by  
12 the law of the State in which it occurs; or

13           “(B) a verbal order that is issued in ac-  
14 cordance with a policy of such agency and that  
15 is provided by a medical director—

16           “(i) in response to a request by the  
17 emergency medical services professional  
18 with respect to a specific patient;

19           “(ii) in the case of a mass casualty in-  
20 cident; or

21           “(iii) to ensure the proper care and  
22 treatment of a specific patient.

23           “(5) DELIVERY.—

24           “(A) IN GENERAL.—A registrant emer-  
25 gency medical services agency may deliver con-

1           trolled substances from a registered location of  
2           the agency to an unregistered location of the  
3           agency only if—

4                   “(i) the agency designates the unreg-  
5                   istered location for such delivery; and

6                   “(ii) notifies the Attorney General at  
7                   least 30 days prior to delivering controlled  
8                   substances to the unregistered location.

9                   “(B) REGULATIONS.—The Attorney Gen-  
10                  eral may issue regulations specifying—

11                          “(i) the types of locations that may be  
12                          so designated; and

13                          “(ii) the manner in which such notifi-  
14                          cation shall be made.

15                  “(6) STORAGE.—A registrant emergency med-  
16                  ical services agency may store controlled sub-  
17                  stances—

18                          “(A) at a registered location of the agency;

19                          “(B) at any location of the agency that is  
20                          designated under paragraph (5); or

21                          “(C) in an emergency medical services ve-  
22                          hicle used by the agency that is traveling from,  
23                          or returning to, such a registered or designated  
24                          location in the course of responding to emer-  
25                          gencies.

1           “(7) NO TREATMENT AS DISTRIBUTION.—The  
2           delivery of controlled substances by a registrant  
3           emergency medical services agency pursuant to this  
4           subsection shall not be treated as distribution for  
5           purposes of section 308.

6           “(8) MAINTENANCE OF RECORDS.—

7                   “(A) IN GENERAL.—A registrant emer-  
8                   gency medical services agency shall maintain  
9                   records in accordance with subsections (a) and  
10                  (b) of section 307 of all controlled substances  
11                  that are received, administered, or otherwise  
12                  disposed of pursuant to the agency’s registra-  
13                  tion, without regard to subsection 307(c)(1)(B).

14                  “(B) REQUIREMENTS.—Such records—

15                          “(i) shall include records of deliveries  
16                          of controlled substances between all loca-  
17                          tions of the agency; and

18                          “(ii) shall be maintained at each loca-  
19                          tion of the agency where the controlled  
20                          substances involved are received, adminis-  
21                          tered, or otherwise disposed of.

22           “(9) OTHER REQUIREMENTS.—A registrant  
23           emergency medical services agency, under the super-  
24           vision of a medical director, shall be responsible for  
25           ensuring that—

1           “(A) all emergency medical services profes-  
2           sionals who administer controlled substances  
3           using the agency’s registration act in accord-  
4           ance with the requirements of this subsection;

5           “(B) the recordkeeping requirements of  
6           paragraph (8) are met with respect to a reg-  
7           istered location of the agency and each location  
8           of the agency that is designated under para-  
9           graph (5);

10          “(C) the applicable physical security re-  
11          quirements established by regulation of the At-  
12          torney General are complied with wherever con-  
13          trolled substances are stored by the agency in  
14          accordance with paragraph (6); and

15          “(D) maintain, at a registered location of  
16          the agency, a record of the standing orders  
17          issued or adopted in accordance with paragraph  
18          (8).

19          “(10) DEFINITIONS.—In this section:

20                 “(A) The term ‘emergency medical serv-  
21                 ices’ means emergency medical response and  
22                 emergency mobile medical services provided out-  
23                 side of an immobile medical facility.

24                 “(B) The term ‘emergency medical services  
25                 agency’ means an organization providing emer-

1           agency medical services, including such an orga-  
2           nization that—

3                   “(i) is governmental (including fire-  
4                   based and hospital-based agencies), non-  
5                   governmental (including hospital-based  
6                   agencies), private, or volunteer-based;

7                   “(ii) provides emergency medical serv-  
8                   ices by ground, air, or otherwise; and

9                   “(iii) is authorized by the State in  
10                  which the organization is providing such  
11                  services to provide emergency medical care,  
12                  including the administering of controlled  
13                  substances, to members of the general pub-  
14                  lic on an emergency basis.

15                  “(C) The term ‘emergency medical services  
16                  professional’ means a health care professional  
17                  (including a nurse, paramedic, or emergency  
18                  medical technician) licensed or certified by the  
19                  State in which the professional practices and  
20                  credentialed by a medical director of the respec-  
21                  tive emergency medical services agency to pro-  
22                  vide emergency medical services within the  
23                  scope of the professional’s State license or cer-  
24                  tification.

1           “(D) The term ‘hospital-based’ means,  
2           with respect to an agency, owned or operated by  
3           a hospital.

4           “(E) The term ‘medical director’ means—

5                 “(i) a physician who is registered  
6                 under subsection (f) and provides medical  
7                 oversight for an emergency medical serv-  
8                 ices agency; or

9                 “(ii) another practitioner who is so  
10                registered and provides such oversight as  
11                authorized by the law of the State in which  
12                the agency operates.

13           “(F) The term ‘medical oversight’ means  
14           supervision of the provision of medical care by  
15           an emergency medical services agency.

16           “(G) The term ‘registered location’ means  
17           a location that appears on the certificate of reg-  
18           istration issued to an emergency medical serv-  
19           ices agency under this subsection or subsection  
20           (f), which shall be where the agency receives  
21           controlled substances from distributors.

22           “(H) The term ‘registrant emergency med-  
23           ical services agency’ means—



1 “(i) an emergency medical services  
2 agency that is registered pursuant to this  
3 subsection; or

4 “(ii) a hospital that owns and oper-  
5 ates an emergency medical services agency  
6 that is registered pursuant to subsection  
7 (f).

8 “(I) The term ‘standing order’ means a  
9 written medical protocol in which a medical di-  
10 rector determines in advance the medical cri-  
11 teria that must be met before administering  
12 controlled substances to individuals in need of  
13 emergency medical services.

14 “(J) The term ‘verbal order’ means an oral  
15 directive that is given through any method of  
16 communication including by radio or telephone,  
17 directly to an emergency medical services pro-  
18 fessional, and to contemporaneously administer  
19 a controlled substance to a member of the gen-  
20 eral public in need of emergency medical serv-  
21 ices outside the physical presence of the author-  
22 izing medical director.

23 “(11) RULE OF CONSTRUCTION.—Nothing in  
24 this section shall be construed—

1           “(A) to limit the authority vested in the  
2           Attorney General by other provisions of this  
3           title to take measures to prevent diversion of  
4           controlled substances; or

5           “(B) to override the authority of any State  
6           to regulate the provision of emergency medical  
7           services.”.

